HOUSE OF LORDS SESSION 2001–02

MINUTES OF EVIDENCE
TAKEN BEFORE

THE SELECT COMMITTEE ON ANIMALS IN SCIENTIFIC PROCEDURES

Tuesday 3 July 2001

THE HOME OFFICE

Mr Trevor Cobley, Head of the Animals, Byelaws & Coroners Unit (ABCU),
Dr Jon Richmond, Chief Inspector, Animals (Scientific Procedures) Inspectorate and
Mr Martin Walsh, Head of Policy Development, Animals Procedures Section

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TUESDAY 3 JULY 2001

Present:

Brennan, L.
Eccles of Moulton, B.
Hunt of Chesterton, L.
Lucas, L.
Nicol, B.
Onslow, E.
Smith of Clifton, L. (Chairman)
Soulsby of Swaffham Prior, L.
Taverne, L.

Memoranda by the Home Office

Background Note on the Animals, Byelaws & Coroners Unit (ABCU) and Animals (Scientific Procedures) Inspectorate

ANIMALS, BYELAWS & CORONERS UNIT (ABCU)

1. As part of the Home Office Constitutional & Community Policy Directorate (CCPD), the Animals, Byelaws & Coroners Unit[1] (ABCU) contributes to Home Office Aim 5:

— Helping to build, under a modernised constitution, a fair and prosperous society, in which everyone has a stake, and in which the rights and responsibilities of individuals, families and communities are properly balanced.

2. In particular, the Unit contributes to two Aim 5 objectives:

— Objective 3: promoting a fairer and more open society in which the rights of individuals are balanced within a clear legal framework;

— Objective 4: providing effective regulation which balances public concern against the needs of industry, commerce and science.

3. It does so, in part, by:

— regulating the use of animals in scientific procedures; and

— providing support to the Animal Procedures Committee.

4. Ministerial responsibility for animal procedures is exercised by Angela Eagle, MP, Home Office Parliamentary Under-Secretary of State.

ANIMAL PROCEDURES SECTION

5. The Animal Procedures Section is responsible for policy on the use of living animals in testing and experimentation, and for the operation of the Animals (Scientific Procedures) Act 1986. It aims to maintain the balance required by the 1986 Act between the interests of science/industry and animal welfare.

6. The Section works closely with the Animals (Scientific Procedures) Inspectorate, which comprises staff with medical or veterinary qualifications, and experience of scientific research. The Inspectorate advises on all licence applications, monitors compliance and acts as the source of professional advice to the Secretary of State.

7. ABCU administrative staff operate the licensing system on behalf of the Secretary of State, processing applications for new licences and certificates and for amendments to existing authorities and revoking licences, as necessary. The licensing team works to a code of practice—known as the Licensing Charter—setting out the standards of service to which the Home Office is committed in operating the licensing system under the 1986 Act. The licensing team processes about 10,000 licence applications and amendments per year.

8. The licensing work is carried out at five regional offices located at Cambridge, Dundee, London, Shrewsbury and Swindon. The licensing team comprises 21 staff.

9. A further five staff provide policy support to Home Office Ministers, including the preparation of responses to Parliamentary Questions, letters from Members of Parliament seeking advice on matters raised by their constituents (Ministers' Cases) and public correspondence relating to the use of animals in scientific procedures.

10. A note summarising the main activities of the ABCU Animal Procedures Section and the Animals (Scientific Procedures) Inspectorate in 2000–01 is provided at Annex A.

[1] NB. Following the recent machinery of government changes, the byelaws function is being transferred to the Department of Transport, Local Government and the Regions.

Animal Procedures Committee Secretariat

11. The Animal Procedures Committee (APC) is an advisory, Non-Departmental Public Body established and appointed under the terms of sections 19 and 20 of the Animals (Scientific Procedures) Act 1986.

12. Its role is to advise the Home Secretary on matters concerned with the Act and his functions under it. The Committee publishes an annual report, available from The Stationery Office and at the Committee's website http://www.apc.gov.uk.

13. The Committee has its own dedicated secretariat, comprising three staff. For organisational purposes, the APC Secretariat is attached to the Animals, Byelaws & Coroners Unit.

THE ANIMALS SCIENTIFIC PROCEDURES INSPECTORATE

1. The Animals (Scientific Procedures) Inspectorate is part of the Home Office Constitutional & Community Policy Directorate and contributes to the same Home Office aims and objectives as the Animals, Byelaws & Coroners Unit.

2. Animals (Scientific Procedures) Inspectors are employed as civil servants to provide professional medical, veterinary and scientific advice to the Home Secretary and his officials in the Animals, Byelaws & Coroners Unit who operate the licensing system under the Act and determine policy. They also maintain a programme of inspections of facilities where work under the Act is carried out.

3. The Inspectorate is composed of registered medical and veterinary practitioners. They usually have first-hand experience of biomedical research and possess higher scientific or clinical postgraduate qualifications.

4. There are currently 21 inspectors based in offices at Cambridge, Dundee, London, Shrewsbury and Swindon. This complement is to be increased to 33 inspectors over the next three years. The Inspectorate works to a code of practice—known as the Licensing Charter—setting out the standards of service to which the Home Office is committed in operating the licensing and inspection systems under the 1986 Act.

5. Effectiveness depends upon ability to gain the respect and co-operation of the scientific community as, to function, inspectors must have access to the current and future plans of scientists. Diplomacy and personal authority are needed as well as formal qualifications and good communication skills.

The Scientific Role

6. The inspector is the "front line" scientific assessor for the Home Office of proposals for programmes of work involving living animals. Applications for project licences made by senior scientists are often complex and may cover up to five years' work. The proposals may be for any work within the entire field of biological and biomedical science, from human transplant surgery to the life history of newts.

7. Proposals must be assessed in detail and challenged where necessary to determine whether the benefits likely to result from the project outweigh the cost in suffering to the animals to be used. To make this judgement, members of the Inspectorate must take a view on the scientific quality of the proposed work, the appropriateness of the animal use and the measures to be taken to minimise suffering.

8. It is often necessary for inspectors to discuss the proposals in detail and at length with the scientists so that the inspector is confident when making judgements that as much as possible has been done to replace the procedures with alternatives not using living animals, to reduce numbers of animals used, and to refine the procedures to minimise pain, suffering, distress or lasting harm.

9. Inspectors use a variety of sources of assistance such as colleagues with expertise in the particular field, computer databases and libraries to help them make the necessary judgements. In more difficult cases, applications for project licences are referred for advice to external experts in the particular field. Advice will also be sought from the Animals Procedures Committee when new or sensitive matters of policy are involved such as the use of wild-caught non-human primates.

The Advisory Role

10. The questioning and challenging of proposals in project licence applications is an essential part of the assessment process, at the end of which inspectors offer advice to the Home Secretary and officials as to whether and on what terms licences should be granted. (The Act does not empower inspectors to issue, or revoke, licences or certificates.) The Inspectorate also functions as a source of professional and scientific expertise in the formulation of policy on the care and use of animals in laboratories.

THE INSPECTORIAL ROLE

11. Inspectors maintain programmes of visits to establishments to check that licensees and others are complying with the terms and conditions of the licences and certificates, and maintaining standards of husbandry and accommodation in line with the provisions of the Codes of Practice. Inspectors are expected to be well informed on all aspects of the work being undertaken in the places for which they are responsible and to develop and sustain a satisfactory working relationship with the 1,000 or so licensees and others in their region.

12. The Inspectorate carries out in excess of 2,000 visits to establishments each year for inspection purposes, spending over 5,500 man hours at establishments where licensed work is performed. The number of visits to each establishment during the year is determined by size and type of work carried out. Two thirds of the visits to animal facilities within establishments are made without notice.

THE REPRESENTATIVE ROLE

13. The Inspectorate exists to help to ensure that the intentions of Parliament in passing the Act are realised. Inspectors represent the Home Secretary and are entirely independent of all interest groups involved in the debate over laboratory animal use.

14. Inspectors advise potential applicants, licensees and others on the 1986 Act and its implementation and liaise as necessary with bodies representing scientists, commerce and animal welfare groups. Liaison with other Government departments and colleagues in other European countries is also maintained.

15. A note summarising the main activities of the Animals (Scientific Procedures) Inspectorate and the ABCU Animal Procedures Section in 2000–01 is provided at Annex A.

Annex A

ABCU/ASPI—MAIN ACTIVITIES 2000–01

(a) DAY TO DAY ACTIVITIES

In 2000–01:

- ABCU and the Inspectorate collectively dealt with just over 10,000 applications for new licences and amendments to existing licences;
- the ABCU policy team dealt with over 500 letters from Members of Parliament seeking advice on matters raised by their constituents (Ministers' Cases), about 150 written parliamentary questions and over a 1,000 letters from members of the public;
- the Inspectorate carried out over 2,000 visits to establishments, two-thirds of which were unannounced, spending over 5,500 man hours at establishments where licensed work is performed.

(b) SPECIFIC ACTIVITIES

Licensing Charter

A revised code of practice—now known as the Licensing Charter—was published in July 2001, setting out the standards of service to which the Home Office is committed in operating the licensing and inspection systems under the 1986 Act.

Annual Statistics

The Statistics of Scientific Procedures on Living Animals Great Britain 1999 were published in August 2000. The following is a short summary of the information published:

- The number of procedures started in 1999 was about 2.66 million, almost exactly the same as in 1998. Eighty three per cent of these were performed using mice and rats;
- The number of animals used in 1999 was 2.57 million, about 24,000 fewer than in 1998;
- The number of procedures involving the use of genetically modified animals rose by 63,000 to 511,000 in 1999, but this was almost exactly offset by a decrease to 1,894,000 in the use of animals with a normal genetic constitution.

3 July 2001] *[Continued*

Inter-departmental concordat on data sharing

When the annual statistics for 1999 were published, we also announced a cross-Government concordat on data sharing. The Concordat encourages Government departments and the scientific community to endorse the principle of data sharing and encourages further work to overcome the practical, legal, commercial and cultural resistance to it.

Alternative tests for skin corrosivity and phototoxic potential

We also announced in August 2000 that licences for tests on animals for skin corrosivity and phototoxic potential would no longer be granted as three scientifically-validated, non-animal test methods are now available.

Home Office guidance for regulatory toxicity testing

The final text of guidance on regulatory toxicity testing was agreed in September 2000 and is available on the Home Office web-site. Members of the Animals (Scientific Procedures) Inspectorate worked with representatives of the British Toxicological Society, the British Society of Toxicological Pathologists and the Department of Health to produce the guidance, which reflects Home Office policy and best practice.

Review of local Ethical Review Processes

On 1 November 2000 the Home Secretary announced that he had asked the Animals (Scientific Procedures) Inspectorate to carry out a review of the local ethical review process. The terms of reference for the review are to review the efficiency and effectiveness of the operation of the Ethical Review Process, and in particular to consider whether the aims of the process have been achieved, what problems may have been encountered, what the resource implications have been and to recommend any changes in the arrangements and to identify best practice.

The review will take account of the views of all of the stakeholders in the process, including certificate holders and licensees under the 1986 Act and animal welfare organisations. The Inspectorate has been asked to report during 2001.

Increase in the size of the Animals (Scientific Procedures Inspectorate)

In March 2001, Ministers announced that the existing complement of 21 inspectors is to be increased to 33 over the next three financial years.

Animals, Byelaws & Coroners Unit (ABCU)
Animals (Scientific Procedures) Inspectorate
Home Office

26 June 2001

Examination of Witnesses

MR TREVOR COBLEY, Head of the Animals, Byelaws & Coroners Unit (ABCU) , Home Office, DR JON RICHMOND, Chief Inspector, Animals (Scientific Procedures) Inspectorate, Home Office, and MR MARTIN WALSH, Head of the Animals Procedures Policy Development Section, Home Office, called in and examined.

Chairman

80. Gentlemen, you are most welcome to come here this afternoon; thank you very much for doing so. As you know, we are holding this particular meeting in private, and I want to put into the record why we are holding it in private. I have received a letter from the Permanent Secretary in the Home Office expressing concerns about the safety of his staff were they to be televised when appearing before this Committee. Evidence today will therefore be held in private. A transcript of this meeting is, however, being taken in the usual way, and will be made public as soon as possible. I emphasise, however, that this decision is not intended to set a precedent for the Committee, either for these witnesses or for any other witnesses. The Committee will remain at liberty to recall these witnesses later in the Inquiry, and consider in due course whether they should be obliged to appear in public at that later date. I would now like to ask the witnesses if they have anything further to add on this matter.

(*Mr Cobley*) Only to thank you, my Lord Chairman, for responding to the Permanent Secretary's letter; and just to emphasise that we have no difficulty with giving our evidence in public—it was only the question of televising and the association of our names with recorded images which caused us concern.

81. We do appreciate that. Thank you very much. Do you briefly want to introduce yourself and your colleagues?

(*Mr Cobley*) I am Trevor Cobley. I am Head of the Animals, Byelaws & Coroners Unit in the Home Office, which has amongst its responsibilities the administration of the Animals (Scientific Procedures) Act 1986. On my left is Dr Jon Richmond, who is Chief Inspector of the Animals (Scientific Procedures) Inspectorate, which works alongside my Unit and advises the Secretary of State on matters under the Act. On my right is Martin Walsh, who is Head of the Animals Procedures Policy Development Section, which is part of my Unit.

82. What opportunities are there for greater openness in the operation of the Animals (Scientific Procedures) Act; and how can communication with and participation by the public be improved?

(*Mr Cobley*) Can I begin by saying, my Lord Chairman, that the Government is fully committed to greater openness and sees considerable advantage in improving openness in these matters. We are, of course, constrained at the moment by section 24 of the 1986 Act, which precludes disclosure of much of the information which we hold in administering the Act; but the Government is committed, in the wake of the Freedom of Information Act, to reviewing this statutory bar—indeed, all the statutory bars which exist in other legislation.

83. What sort of information are you not able to disclose?

(*Mr Cobley*) Any information that is given to us either in confidence or which we believe to have been given in confidence.

84. Is this commercially sensitive information?

(*Mr Cobley*) No, it is any information at all believed to have been given in confidence. Obviously there are concerns about identifying people who carry out work under the Act; and places where that work is carried out are not necessarily in the public domain. As recent events have demonstrated, some of those establishments are targets for animal rights extremists. So there is a balancing act to be done here between the needs of commercial confidentiality and personal security, and the greater good of making things more open. In the context of reviewing that we have been looking at some possible ways of making things more open. One of the things we have been looking at is the possibility of requiring applicants to produce what we call "lay summaries"—that is, summaries of their applications in layman's terms which would not contain any commercially sensitive or personal security information—and making those available perhaps on our web site so that people could see the kind of applications that are made. That is at the early stages of the thought process. I am just giving that as an example of the kind of things we are looking at. We are also looking this year at our annual statistical publication (and I am sure copies of that have been made available to you) to see how we can improve it. We are conscious it is not the most user-friendly document. With our statisticians we are going to be looking at how we can improve it; and, again using modern technology and web sites, how we can make the statistics more accessible. Those are two possible areas. We think that the scientific community, those carrying out experiments and scientific procedures, also have a part to play in making things more open. There are obviously constraints again from the personal security and commercial confidentiality point of view, but I think ministers would feel that there is scope for those parties to explain more about the benefits of research. I think that is probably it.

Lord Lucas

85. Could you give me an idea of timescale and examples of how you might become more open? Have you got a commitment to do that within the next 12 months?

(*Mr Cobley*) The statistics have a longer lead-in period. If we decide we want to collect them in a different way we have got to give notice to people we collect the statistics from. We are hoping within the next 12 months to come up with ideas of how we might make the statistics more user-friendly. Similarly, ministers have a commitment, as I have said, to reviewing all statutory bars, including section 24; so within certainly 12 months they would be bringing forward proposals.

Lord Taverne

86. Openness and transparency are highly desirable but publicity, surely, is something else which is very important; because the public does not as a whole, I believe, realise quite how tough and effective the regulations governing experiments in this country are. There does not seem to be much Government publicity about it. They think of lots of animals being tortured all the time. The proportion of animals which are subject to mild discomfort is enormous; and the number of animal experiments carried out on mice is overwhelming. This kind of information should surely be much more public. What can the Government do, what can the Home Office do, to publicise this much more adequately?

(*Mr Cobley*) It is something which goes beyond the scope of the Home Office, because we are the regulator and we can explain, and indeed we do have leaflets and information available, about the way in which we exercise the controls; but other departments have the lead in requiring research whether it is for pharmaceutical testing or fundamental research, the kind of things the Department of Health and other departments fund. Collectively ministers are looking at ways of increasing public awareness in just the way you describe; because it is clear from public opinion polls (and I think you are familiar with the one which MORI undertook for the Medical Research Council) there is not an understanding of the rigorousness of the controls. When asked to describe the kind of controls that they would expect to see, I think some of the focus groups actually described more or less what we have got without realising that it was already in place.

Earl of Onslow

87. You said at the beginning that people tell you things in confidence which were not necessarily commercially sensitive, and that this you found difficult under section 24. Is it not better that you should be told things in confidence so you can watch it, and then it should not actually become public? I am a great believer in the public having every access and right but, equally, I think there can be occasions when the public's right to know can be actually very dangerous and abuse the sensible process of government. How do you balance those two?

(*Mr Cobley*) It is difficult.

88. I am supposed to be a Liberal, by the way!

(*Mr Cobley*) It is difficult, particularly in an area like this, which is why I was moving towards the idea of a summary which will have been agreed with the project licence applicant, which everybody agrees contains helpful information, is transparent, and safeguards the considerations I have mentioned.

Chairman

89. Is there any reason why statistics should not be compiled to show (a) how many animals, and what kind, suffer mild, moderate or severe pain; and (b) for which purposes these animals were subjected to such pain? In other words, to introduce some cadence into it so the public would get some feel for the range and extent and the different orders of magnitude?

(*Dr Richmond*) It is something, my Lord Chairman, which I agree there is a need for. The problem with publishing purely quantitative statistics is the public and politicians tend to measure progress by the numbers of animals used, which is not necessarily the best index. We have looked at other systems used in other countries, such as Holland, but we can see no efficient way of collecting truly informative information on this subject. For example, the severity limits which we accord to the individual procedures which are done reflect the very worst that may happen to any animal subjected to that procedure. Simply reproducing the number of animals against the severity and length of procedures would not inform the public about the level of suffering that animals actually experience. The only way to gather that information would be to actually collect the information retrospectively rather than prospectively. These are things which may come up when we review how the statistics are compiled.

Lord Taverne

90. Surely you have some sort of idea of the number of experiments which actually involve only minor discomfort in the mild category? Is that not something you would publicise? For instance, the very fact that anything comes within the severe category, even if only one out of ten cases does actually suffer severe discomfort, surely this is something you can publicise to give the public a much better idea of what is going on?

(*Dr Richmond*) I think there is scope for looking into that and considering what can be done.

Lord Soulsby of Swaffham Prior

91. On the question of publicity and communication with the public, I must declare that at one time in my life I was a research scientist, with laboratory animals, and there is a level beyond which (in terms of security) you cannot go. Obviously there is commercial security that affects commercial organisations that are looking at compounds; but there is also scientific security. A lot of scientists do not particularly want their ideas that are put forward in a project application to be known to the general public. It is rather like a peer review situation—that you want to keep your good ideas to yourself; not that you want to mislead but there is a point where you cannot be too open to even your peers, as a matter of fact, and certainly not to the general public. How do you manage that scientific security, of the individual wanting to do research and yet be somewhat concerned about declaring everything he wishes to do?

(*Dr Richmond*) My Lord Chairman, at the moment we have no problem. Section 24 is a statutory bar to disclosing such information. Scientists are extremely open in telling us what they would like to do and why. They are concerned that the Home Office has much more information about their ideas, plans and projects than any other regulatory authority in any other country. It is true to say that we do regard, if you like, intellectual property and academic property as being as important and should be kept as secure as other things we normally consider to be commercially sensitive.

Lord Soulsby of Swaffham Prior *contd.*]

92. You would hope that that would still pertain whatever new developments you might have in the running of the Procedures Act?

(*Dr Richmond*) I would think that would be a sound way to proceed.

Earl of Onslow

93. We were talking earlier on about severe pain, mild pain and irritation. If I go fox hunting and I jab my horse in the ribs with a set of spurs he jumps a fence—to him it is nothing; if I did that to you, you would go "Ouch" and go to the doctor. How do we actually measure and how do we know what is severe pain to a mouse, and what is severe pain to a horse, cow, dog or beagle? I accept I know nothing about this, and I am asking the question from the point of view of the ignorant.

(*Dr Richmond*) My Lord Chairman, I think we understand that, no matter how clever our cognitive neuroscientists have become, we will never know what animals actually experience. We do make the assumption that any process or any pathology which would cause pain to man has the potential to cause an animal which had the correct neural architecture and infrastructure to perceive some amount of distress. We tend to talk about pain, suffering, distress and lasting harm. In North America the word "suffering" is eschewed because as you do not know what the animal experiences the North Americans do not use the word "suffering". If we cause man pain, either in the process of or as a consequence of procedures, we would make the same assumption for the animals to which the procedures are applied.

Lord Hunt of Chesterton

94. There was a film produced by Professor John Martin, University College, which did explain a lot of these things. If members have not seen it I would suggest that it is an extremely informative video about the whole process. He goes through experiments and the inspection process. I understood from that, if the procedure would involve extreme pain to the animal, according to the argument about the human, essentially that would not be allowed. Are there any experiments where considerable pain is allowed? One does recall, in my case, varies illnesses and the doctor sometimes saying, "We're not going to anaesthetize you because we want to get a reaction from you and this is part of the diagnosis. Does the same situation happen with animals, or essentially are all really painful procedures forbidden?

(*Dr Richmond*) The legislation, my Lord Chairman, forbids the licensing of any procedure which is calculated to cause severe pain or distress that cannot be alleviated. There can be no surgery without anaesthetic. The legislation also requires that, whatever the procedure is, it must be done under appropriate anaesthesia or analgesia, unless good cause can be shown for that intervention being more of an insult than the procedure itself.

Baroness Nicol

95. I wonder whether some attempt is made when an application comes in to determine whether or not that is going to be a painful experiment. Is it done as far back in the process as that, or do you wait until somebody has started?

(*Dr Richmond*) My Lord Chairman, it is done at the application stage. My inspectors are all either medically qualified or veterinary surgeons. Indeed, the legislation only allows us to license things which *may* have the potential to cause pain, suffering or distress or lasting harm. We do occasionally discuss research proposals which, in our view and in the Minister's view, will not cause pain, suffering, distress or lasting harm. Those things—for example, some dietary studies or some simple observation studies—can be done without Home Office licence.

Chairman

96. Do you consider it acceptable that the time taken to process applications is considerably longer in the UK than abroad; how could applications be expedited without adversely affecting animal welfare?

(*Mr Cobley*) We have to draw a balance between the strong regulatory regime, on the one hand, and the needs of the scientific community, on the other, in processing licence applications. Secondly, different countries operate very different regimes. Various figures have been bandied around but we are not always comparing like with like. For example, as you are probably already aware, the United States does not regulate the use of rats and mice, which comprise some 85 per cent. of the animals used in procedures in the United Kingdom. We are well aware of the need within the strong regulatory regime to process applications as efficiently and speedily as possible. As I am sure the Committee is aware, concerns were expressed last year by a group of scientists about the comparative length of time which needs to be taken; we have progressed that within the ambit of the Prime Minister's Pharmaceutical Industry Competitiveness Task Force. As a result of that, we have been able to implement a number of measures which will, we think, speed up the licensing process without being to the detriment of animal welfare—in fact in some ways we think it will enhance welfare.

97. Could you give us one or two examples?

(*Mr Cobley*) Yes, I can indeed. First of all, we have revised our project licence application form and produced much better notes for guidance which are already in use, and the response to that has been very positive. The Chief Inspector has issued guidance on the local ethical review process part of the procedure. I do not know whether you are familiar with that, but it has been seen as a stage in the process which can delay the application. It is not one within our direct control, although we require it. The way in which it is actually carried out is a matter for the establishment; but the Chief Inspector has issued some guidance. Those are two examples. We have other things in the pipeline for the longer term.

Lord Taverne

98. I want to ask about more detailed delays caused by the particular form of the application. First of all, some time ago in August last year Professor Purchase did some comparative work and he showed that delays in the United States (admittedly perhaps for different experiments) took 6-7 weeks, Germany 15-19, UK 28-33 weeks. First, were those figures accurate; and, second, how far are they now out-of-date?

(*Mr Cobley*) I do not think we would agree with the UK figures. We are not in a position to comment on the other countries. There may be some applications which take that length of time, partly because of the length of time in the local ethical review process. I think his figures were based on when the project started life as an idea within an establishment, and not just when they reached the Home Office.

99. But the complaint of a lot of research workers is that it has got very much more bureaucratic: one not only gets the licence but one has to specify which animals are being used when an application is made perhaps for a five year study period. Obviously in the course of the research different kinds of applications develop. For example, if you are using a rat instead of a mouse you lose your licence. It leads to something like up to ten different amendments for a licence, and each application for an amendment probably takes ten weeks. You get an enormous amount of delay and, in the meantime, animals die and animal welfare actually suffers through the bureaucracy. How far is this a fair criticism made by research scientists?

(*Dr Richmond*) Firstly, Professor Purchase's survey was a survey of opinion at a neuroscience conference. People were asking how long they recollected it took to get authorities to do the work. We have actually analysed our own performance data, and the average time between receipt of a project licence application and granting is less than 40 working days; there are some cases that go beyond that. We have also established that for around half of that time the application is actually back with the applicant asking for clarification or supplementary information or some explanation. We think our performance figures are not as bad as portrayed in Professor Purchase's paper. To try and avoid unnecessary amendments and unnecessary delays we already provide standard minimum severity protocols for licensees to use for common procedures. We have issued guidance on how to write and prepare low maintenance applications that do not need constant minor technical amendments as work progresses.

Lord Soulsby of Swaffham Prior

100. Could I come to the question of timing with respect to research electives. I have heard the complaint in Cambridge, where we are going in two or three weeks' time, that students doing research electives of maybe only eight or ten weeks' duration complain that it takes eight to ten weeks to get a licence by which time the research elective is over. Not only is the time taken to get it all set up, but it is also costly. Is there any way that can be speeded up to allow the necessary introduction of research, and especially medical and veterinary courses where there is an urgent need to get students interested in research endeavours and research careers?

(*Dr Richmond*) My Lord Chairman, it generally does not take very long to process a personal licence application; but we do have mandatory training requirements for personal licence applicants. It may be that the training is the thing which delays student applications. When you discuss these things in Cambridge you might explore with them whether or not that is the true cause of the delay, and whether or not the training could be done at an earlier stage in the undergraduate course.

Earl of Onslow

101. This seems to me completely the wrong way round to go at it. Would it not be much better to say, "Laboratory, you can do basically what you like. We trust you. These are the guidelines down which you go, and if you breach those guidelines you lose your licence"; as opposed to you guys saying, "Every time you do an experiment on a mouse's fingernail we have to get a detailed piece of paper saying what you do". It seems to me you should trust people in high grade biological research stations. These people are grown-up; they should be trusted and we should therefore say, "Trust those people and if they breach that trust they lose their licence and they lose their revenue and livelihood". Is that not a much better way of doing it? After all, it is how we governed the Indian Empire. We allowed people a guideline, and if they breached it they lost their good name.

(*Mr Cobley*) That is a possible approach, but it is not the one at present chosen by Parliament.

102. That was not the question I asked. You are going to get the lead role in *Yes Minister*! Would that not, in all honesty, be a more sensible way of doing it?

(*Mr Cobley*) I am not trying to duck the question.

103. You are succeeding beyond your wildest dreams!

(*Mr Cobley*) There is the question of public confidence. We have already talked about the concerns which are expressed by the public. Even supposing that it was an efficient way of doing it, and perhaps the Chief Inspector could comment on that, I am not sure whether it would command public confidence, which I think is important.

Chairman: We can speculate on that until Kingdom come!

Lord Hunt of Chesterton

104. Regarding representative bodies, scientific societies, the Royal Society and the Institute of Biology, do you have discussions with them about the level of bureaucracy? Are they making protests along the lines of Professor Purchase, or are they accepting your position that the level of control is about comparable with the international standard?

(*Mr Cobley*) My perception is that they are in favour of the system of controls we have in this country. There is a pay-off for them because they are able to say, "We are rigorously regulated". They are obviously interested in ensuring that regulation is carried out as efficiently as possible. We have had discussions with them both bilaterally and through

Lord Hunt of Chesterton *contd.*]

the task force I mentioned earlier on. We have agreed indicative processing times of seven weeks for straightforward applications within the Home Office. It is my understanding that they are content with that period and regard it as competitive as compared with other countries.

(*Dr Richmond*) I do not think there is any sector which we regulate which would like to see any change which compromises the welfare of animals. I think what people expect and are entitled to is efficient and effective regulation. We do have regular meetings with the main stakeholders. In addition, we are playing our part within another group called the Expert Group Efficient Regulation, which is a third party group charged with looking for further efficiencies within the system.

Baroness Nicol

105. I think we have been told that you had 10,000 applications between the years 2000–01. Can you tell us how many of those succeeded; and of the ones that did not succeed why did they fail? Is there any indication that either they did not understand the guidelines or that they were deliberately trying to get round them?

(*Dr Richmond*) We receive approximately 600 project licence applications each year. We generally begin by speaking to people about the idea at the concept stage, and pointing out potential difficulties the work might raise if licensed, identifying the areas where we would expect more information, greater clarity and more refinement. We find the attrition rate is highest between the concept stage and the application stage. When we receive applications we find that almost invariably we have to meet with the applicant to clarify some technical issues and to discuss whether or not further refinements can be made. We are looking at the moment at the common reasons why we have to go back to establish whether or not we need to change the guidance to applicants; but preliminary information suggests that we are probably supplying the right information in the notes to applicants. A small proportion of applications do fail, and authorities are not issued. It may be because we are not satisfied about the scientific validity of the work. It may be that we do not believe the potential benefit exceeds the likely cost. It may be we believe that further refinements can be made but the applicant does not agree. It may be that we believe that the information required to test the hypothesis that has been raised is already in the literature.

Lord Lucas

106. You gave some generalities there; could you give us some examples of the sort of things you have to correct?

(*Dr Richmond*) We find, for example, that a common failing is not to mention post-operative analgesia. It turns out more often than not that the problem was that it was not written into the protocol rather than that it would not have been done. We sometimes find people's literature searches have been imperfect or done electronically and missed literature published before 1974. We have found some applications which are really duplicating work which we have already established is in the published literature. I do not want to give an example of that, but that is something we have seen.

Lord Taverne

107. I do not want to ask too many questions but this is central to the whole of our enquiry and there is one further point I wanted to ask. Mr Cobley said that the public wanted this kind of detailed control. I am sure the public does not know exactly what detail you require—the specification about animals to be used in each particular application. If you were a little more gentle, would you not still be able to secure the welfare of animals? Is it not true that when delays cause the death of animals, and undoubtedly they do in most cases, you are actually being counterproductive with your detailed control?

(*Dr Richmond*) My Lord Chairman, I think we are looking for ways of dealing with things efficiently. We are trying to make sure that no animals suffer because of unnecessary bureaucracy within the system. We have tried to offer assistance by offering minimum severity protocols and running workshops on how to write low maintenance applications. We do find on occasion that the excess detail which we get in applications is written in by the applicant rather than required by the Home Office.

Earl of Onslow

108. You mentioned that maybe you turn it down because of extra cost. We know how absolutely totally brilliant the Civil Service has been over cost analysis and getting costs right and getting costs wrong. Why should this be of any interest to you whatsoever? With the greatest respect, it is something which the Civil Service has almost universally got wrong.

(*Dr Richmond*) I used the term "cost" to refer to the animal welfare costs.

Earl of Onslow: Under those circumstances I misunderstood you.

Chairman

109. We must now proceed. I think the next question is very brief, really, we just want a response to that, if you do not mind, Dr Richmond. What is the status of Inspectors within the professional scientific community, how are your inspectors perceived, as sort of OFSTED types?

(*Dr Richmond*) We have established a relationship with those that we regulate based upon trust. My staff are all either medical or veterinary graduates, we have either higher professional and/or higher academic qualifications. Indeed we currently have 21 staff with in excess of 80 academic and professional qualifications between us. We try and establish a rapport with those we regulate. We try and get from them what they are trying to do and why. My perception is that we do have the trust and respect of those we regulate and they are happy to deal with us almost as peers, although we can never be as expert as any individual applicant in their own field.

Chairman *contd.*]

110. You are going to expand the inspectorate, I think I am right in saying. Is there a significant pool of willing recruits out there to enable you to come up to your normal standard?

(*Dr Richmond*) Over the next three years we will be appointing 18 new staff—12 additional staff, and six to replace staff who are due to retire. We advertised recently to appoint the first six and we had 42 applications, 17 were good enough to interview and 14 have passed the board as suitable for an appointment.

Chairman: Thank you very much.

Lord Soulsby of Swaffham Prior

111. Within the inspectorate do you have people who specialise in special areas like GM work and other work in addition to their general application and administration of regulation?

(*Dr Richmond*) Although individual applicants often believe they are dealing with one inspector we do actually function as a team. We expect the inspectors to arrive equipped with specialist knowledge and maintain this and make it available to us. We expect staff to develop new areas of expertise and again act as focal points to deal with organisation and to deal with specialist applications. There is a large amount of internal referral within the Inspectorate which is invisible to those on the outside. For example, some classes of application will probably be passed at some stage to a single inspector, so we have not only quality advice but consistency of advice as well.

Baroness Eccles of Moulton

112. Could I, please, ask Dr Richmond why it is necessary to expand the inspectorate by 12 over 21, because it does seem to be quite a substantial expansion.

(*Dr Richmond*) The business case which backs up the expansion was based upon three main streams of thought. One was that it will help provide more efficient regulation and help reduce any delays which currently occur, because we have staff with so many things to do we cannot always process things as they come in. We would also like to do more inspecting and spend more time with the people we actually regulate. More importantly, we would like to become much more proactive in actually helping promote the regulatory regime and how it operates by actually participating in third party initiatives to improve the welfare of laboratory animals and the quality of science done with the laboratory animals. Also using our own initiatives to run our own programmes and projects to do the same. We have a large amount of expert knowledge and we have a large amount of information about what we perceive to be contemporary best practice, but at the moment we just do not have the resources to codify and use that to the best effect.

113. Would those extra inspectors and the programme that you outlined also include the ability to identify areas where there would be duplication in work already done by granting a licence?

(*Dr Richmond*) I think that is something that we already try to do. It is something which is actually quite difficult to do because applications which are superficially very similar are often quite different in terms of detail. There is also the feeling that science is not science unless more than one person has established that the same phenomenon occurs under the same situation. What we try to root out is unnecessary duplication—sometimes people do not know they are trying to reproduce the work of others.

Lord Lucas

114. What happens to the inspectors when they leave you; do they go on to careers in industry or in academia or is this the end of the line?

(*Dr Richmond*) Historically we have lost inspectors for two reasons, some people have not settled within the organisation and have left within a year, otherwise people have retired at the end of their career. We have not lost staff to industry or academia.

Baroness Nicol

115. The increase in numbers; I do not know how you arrived at that particular number to increase it, are you satisfied that it is going to enable you to do everything you really need to do in order to see that the legislation is properly enforced?

(*Dr Richmond*) I think it is.

116. There is the chance of a lifetime here for you.

(*Dr Richmond*) I find myself in two minds here. 12 additional staff should allow the Inspectorate not just to do its current functions to its best effect, it should actually allow us to raise the standards, not just ensure that minimum standards are imposed and met. Finding 12 additional staff is likely to be a challenge. I will be very pleased if we do find 18 suitable people over the next three years to do the job. At the same time finding accommodation, training, and ensuring consistencies in managing those extra staff is probably about as much as we will be able to manage over the next three years. It takes three months to train a new inspector and during that time they consume inspectorate resources rather than contribute to inspectorate resources. I think 12 was a settlement which will set the inspectorate up to do things as well as they can be done.

Earl of Onslow

117. I am coming back to the question I asked before. It seems to me that if the Inspectorate can spend much more time actually in the laboratories watching what people do, as opposed to reading bits of paper in London and saying what they wish to do, if you do more in licensing research establishments rather than individual experiments you will get a greater control of quality and less bureaucracy. The bureaucracy on this does seem to me, from what I heard you say, to be very, very considerable and it is nothing other than counterproductive. Nobody is arguing the importance of animal welfare, nobody is arguing about that, it just seems to me we are going

Earl of Onslow *contd.*]

about it slightly the wrong way. Please comment? You are quite entitled to say, "Lord Onslow you are talking rubbish", I do not mind you saying that in the slightest.

(*Dr Richmond*) I will not say that.

Chairman

118. Go on.

(*Dr Richmond*) What I will say is that when you look at the value the inspectorate adds to animal welfare, a major contribution at the planning and design stage rather than just correcting things when they have been done, and if you look at the annual statistics for 1998 you will see that we published 10 case studies of the value that was added to welfare and science during the assessment process.

Lord Brennan

119. With the increase in numbers you expected you could be more proactive; is there a role for the Inspectorate either at licensing or inspection stage to question whether there are other means of experimental investigation in the use of animals? Is the Inspectorate equipped to make such a decision, if it is not should it be?

(*Dr Richmond*) That is one of our primary functions. We spend a large amount of our current resources reviewing applications and looking at opportunities to replace animals and refine procedures.

120. How are your staff equipped to cope with the science?

(*Dr Richmond*) We maintain our links with any number of professional bodies and societies. We spend about 10 per cent of our time on continuing professional development, which is anything that the inspector needs to know to do the job properly. We send representatives to most major conferences where alternatives are actually being discussed. I am actually involved in helping to organise the 4th World Congress on Alternative Methods. We like to send people not just to listen to these things but to contribute. Having the additional resource, we will become a more active contributor rather than a group that just goes and listens.

Lord Taverne

121. You said earlier that some of the applications were turned down because you were not satisfied about the benefit of the work. Are you really in a position to judge that better than the peer review which proposals have to undergo anyway, or the various detailed examination of somebody's proposed work that institutions would have to carry out?

(*Dr Richmond*) I would not say better placed to judge, I would say certainly well placed to challenge and explore whether or not the potential benefit is as anticipated and predicted by the applicant.

Lord Hunt of Chesterton

122. Can I ask two questions? First of all, you, I think, described very well and I think made a good case for the expansion of the Inspectorate, and I know that from having managed in the scientific side of the Civil Service myself. One of the other questions which I think is important—because there seems to be some difference in how this whole matter is perceived on the continent, because in training people they seem to be much more suspicious about using animals in education and some areas of experimentation—is the question of working with colleagues in Brussels. Is that part of your job? You say you were talking at international conferences, can you give us some idea of how the drift is going? Obviously, as we work closer and closer with Europe if we have practices that are very different it will be more difficult. Perhaps both of you could answer this question?

(*Dr Richmond*) We network with our European colleagues and peers at meetings of national competent authorities which are hosted by the European Commission. The Inspectorate has also contributed to training courses, on EU Directive 86/609 the relevant Directive for the candidate countries waiting to join the European Union. We also liaise with other regulatory authorities in other countries. I am just back from two trips to North America to look at systems in addition to contributing to training courses that were run. At our last inspectors conference—we have two continued professional development conferences per year—we had a representative from the USDA, our equivalent in the United States, telling us about how they do things. We do try and benchmark ourselves against other organisations and look for good ideas we can incorporate into our own practice, and try to pass some of our ideas on to others in the same field.

123. Is our position on this distinct from those of our continental colleagues or is it very similar in the use of animals?

(*Dr Richmond*) In terms of regulatory systems every country has evolved its own system; even within Europe implementing the same Directive different systems apply.

124. My impression is that it might be different in some other European countries.

(*Dr Richmond*) Some of the other regulatory regimes do not have a very strong specialist and scientific input to the assessment programmes, whereas in the United Kingdom we have a strong scientific input into the assessment of applications. I am not sure I am addressing your question.

125. Do you allow more animal experimentation in the United Kingdom than, let us say, Austria?

(*Dr Richmond*) I have no detailed knowledge of the practice in Austria. I can say that we only allow that which can be justified under the terms of the legislation.

Chairman

126. Perhaps we can move on to something relating to Lord Onslow's questions; where do inspectors go after they leave you, and you said they

Chairman *contd.*]

retired? Are they required to make a public declaration of any interests or connection to interests, research establishments and relevant charities and pressure groups; if so, how are these made public?

(*Dr Richmond*) We are civil servants bound by the Civil Service Codes of Practice with regard to certain conduct. We have no continuing links to industry or academia. We are involved with a number of charities and other organisations which promote human animal science but we do not compile or publish any central register.

Chairman: Could I move on to the next question.

Lord Taverne

127. Has there been any case in which you have had infiltration by some of the extreme animals rights' groups, who appeared to be very moderate, sensible people; has there been any case at all?

(*Dr Richmond*) My Lord Chairman, no.

Lord Taverne: No.

Chairman

128. The balance of paperwork, we have touched on this, and the number and length of visits undertaken by the Inspectorate, have these changed exceptionally over the last 10 years? I am not looking to your planned changes, but historically what has happened?

(*Dr Richmond*) They have. I will take you back as far as 1985 when the current legislation was going through Parliament. Under the previous legislation, the Cruelty to Animals Act 1876 there was no equivalent of the project licence and the Home Office actually knew very little about the science that was being done. Back in those days a typical inspector would spend three days a week inspecting and two days a week on administration and other tasks. I have detailed figures for the last four or five years which show *me* that year-on-year we seem to be spending about 40 per cent of our time on the inspection process, about 45 per cent of our time on the assessment process and about 15 per cent of our time on other duties, half or more is continued professional development.

Earl of Onslow

129. In other words there has been a sharp fall, 40 per cent per week is two days and previously it was three days; what has happened is that the Act has made sure you sit writing paper to each other for one day longer than you did in 1876. I accept that that is a slightly tiresome way of putting it, but that does seem to be exactly what you said.

(*Dr Richmond*) I think the greatest contribution the Inspectorate makes to laboratory animal welfare is at the design and planning stage. I hesitate to say that we should be taking resources away from that at present to put back into inspection.

Chairman

130. Dr Richmond, could you make those figures available to us in some detail. Thank you very much. We are coming to a crunch question in terms of Lord Onslow's preferred regime, namely you would be entitled to make unannounced visits. Could you give us a feel for what an unannounced visit is? Does the chap or woman turn up and the doorkeeper turns him or her away or does he have a pass which enables him to go straight in, or what?

(*Dr Richmond*) We carry identification which is sufficient to get us into any designated establishment in the country, although we are seldom asked to show it. Around two thirds of our inspections are without notice. At the moment we conduct around 2,100 visits or inspections a year, spending some 5,700 contact hours with people we regulate and the people who care for the animals. Although the visits are unannounced they are not random and not unplanned. We do prepare for visits: we look for loose ends; we look for what the previous findings were; we consider what has come through correspondence and telephone calls since the last visit and we decide what aspects we will look at in detail. The inspection would normally begin at the animal facility, which would be looking at the animals with the animal care staff, asking for explanations of what we were seeing, asking what has been happening since the last visit. We would normally track down any animal which had been issued for use that day and go and watch the procedures being put forward. We would generally then have a shopping list of minor things we wanted to know more about and go and talk to individual licensees and scientists about those things. Most places also have a Home Office liaison officer who keeps track of individuals who would like to talk to us on site and we then pick up those things and deal with them.

Lord Taverne

131. I am sure the public would be delighted to know that you made so many unannounced visits, and I believe they do not. Is it not something you ought to be trumpeting from the rooftops since you are carrying out 2,000 of these visits per year and spending 5,700 hours on checking that animals are properly looked after?

(*Dr Richmond*) It is something we repeat at every opportunity but it is difficult to communicate that to the public. I have tried when journals or newspapers have published pieces about animals to offer a small editorial or piece on the regulatory system and how it it implemented. I am afraid good regulation is not news.

Lord Taverne

132. When we saw the APC they said that there was a great difference in quality between establishments; that although they all met the law, you would go into ones which were places they did not care to linger in, and others where they felt that things were being really well done. Is that your experience too? If so, how would you bring everybody up to the best?

Lord Taverne *contd.*]

(*Dr Richmond*) My Lord Chairman, there is indeed diversity. We have codes of practice which mandate minimum standards of care and accommodation in places. We are working at the moment within the Council of Europe on the next generation of standards of care and accommodation for laboratory animals, which we hope will make better provision than some of the current provisions. We make sure that not only are the current minimum provisions implemented or exceeded, but that anything which is technically compliant but might nevertheless impair the welfare of the animals or the quality of science that is being undertaken is remedied. We have no statutory authority to require all places, however, to be as good as the best, but we are keen to identify and spread best practice and an awareness among the user community that compliance with the minimum standards is not necessarily something which they should be satisfied with.

Lord Soulsby of Swaffham Prior

133. What would be the procedure for a visit, announced or unannounced, from a complaint from the public or from one of the organisations against animal experimentation? Would you act on that, or would you look at the evidence first and then follow it up with an unannounced visit?

(*Dr Richmond*) My Lord Chairman, it would depend on the context and the circumstances. We do look into things which are raised by the public or other third parties as concerns. If there is any implied criticism of the inspector involved, we send in an inspector who is not part of that regional team or the main management of that regional team, to try to establish the facts for ourselves.

Earl of Onslow

134. I was rather worried when you said just now that there was a difference between the best and those who just passed the standard. By the tenor of your voice, I rather gathered that they should not have passed, but you have got to pass them by the Act, and there were others who should have passed. Is there anything in the Act like in the old Army Act—conduct prejudicial to good order and military discipline—so if there was anything which you did not like you could stop it? Is there anything in the Act which would allow you to stop anybody so that even if they pass it, you think they should be doing better? I know that is rather an old-fashioned view, but there is some merit in it.

(*Dr Richmond*) My Lord Chairman, there is no such provision, but we do have influence, even though we may not have power.

Baroness Eccles of Moulton

135. Dr Richmond, you mentioned some people called the Home office liaison officers, did you not?

(*Dr Richmond*) Yes.

136. They seem to me perhaps to be quite crucial people when it comes to communication between the various establishments and the Home Office. Could you say a little bit more about them?

(*Dr Richmond*) Home Office liaison officers have no statutory role under the Act, they are an administrative convenience. Many establishments which conduct animal research on any scale have found it to be much more efficient and effective to have a single point of contact within the organisation, rather than 35 members of staff dealing independently with the Home Office. We do not require that establishments have such people, but we do find that they are an extremely effective way of gathering information and distributing information.

Lord Lucas

137. If I am doing an experiment on animals, how often would I expect to see one of your inspectors?

(*Dr Richmond*) My Lord Chairman, the average facility—if there is such a thing—would be inspected approximately four times a year. There are some facilities which are only used seasonally or perhaps not even used at all in the course of a year, and they may be visited only once, but each establishment is visited at least once. There are establishments which work on such a scale or perform work which is sufficiently contentious that they will be inspected more than once a month.

Lord Soulsby of Swaffham Prior

138. Could I just ask very briefly, about your experience with the ethical review committees? Do you find them helpful? I know your inspector will attend the meetings, but are they proving to be a useful and effective instrument in the whole of the process?

(*Mr Cobley*) Perhaps I could remind the Committee that we are in fact in the process of reviewing the ethical review process to find out just that point—how far have they contributed to the process, and whether they are unduly bureaucratic—but the Chief Inspector has some direct experience of that.

(*Dr Richmond*) I would say two or three very complimentary things about the ethical review processes, and even today, though they are still imperfect, this would be right. The first is that they have provided visible and active management support for named veterinary surgeons and named animal care welfare officers who are the key welfare people within the establishments, so they have raised their profile and raised the authority given to them by management. They have tackled and to some extent resolved a number of long-standing problems which management did not previously necessarily take seriously, and we are now of the opinion that we are beginning to see some improvements in the quality of applications which have been subjected to the ethical review process before being submitted to the Home Office for processing.

Lord Hunt of Chesterton

139. Am I right in saying that some of the establishments your inspectors visit are ones that are the targets of animals rights activists, and that on those occasions, where the activists are literally outside, like Huntingdon Life Sciences, presumably your inspectors must be concerned? Is there any change in your practice or procedure? Would you like to comment on that in any way?

(*Dr Richmond*) My Lord Chairman, we do indeed inspect those establishments, and we try to maintain whatever inspection regime we think they merit, regardless of the activity outside the gates. We take a number of measures, which I will not discuss in detail, to make sure that our personal security is not compromised—and I make a point of sharing responsibility with the inspectors of those places and I also visit them myself.

Lord Taverne

140. I want to come back in a moment to the ethical review process. In the course of this process will you also be looking at how far they should be involved in each amendment of an application when research takes an unexpected turn? Is that something you are looking at? That is one of the complaints, as I understand it, which is that they greatly exacerbate the delays by being constantly consulted at every occasion.

(*Mr Cobley*) Certainly it is within the terms of reference.

Lord Lucas

141. When will that review be completed? How will the inspection be carried out? Will they be expected to report by the end of this year?

(*Dr Richmond*) The consultation is finished. We have had over 200 responses to the public and stakeholder consultation. We are in the process of conducting site visits to a cross-section of establishments to talk to all the people involved or affected by it on site, to get the opinion of the people who are actually involved and affected by it. We expect that the site visits will finish in two or three months' time, although we might increase the size of the sample if we find that there are some things which are difficult to explain from the information available. However, we do intend to have everything written up and reported to Ministers before the end of the year.

Earl of Onslow

142. You touched very briefly on the security of your inspectors. It is something obviously which would concern me and, I would assume, everybody else. How worried are you by it? These people are evil. It is quite hard to exaggerate how evil they are, I think, and the viciousness with which they behave. How worried are you? Are you happy with the level of security and of protection which your inspectors receive?

(*Dr Richmond*) My Lord Chairman, in response to that I would only like to say that I take the personal security of myself and my staff seriously and would hope that nothing that I would ask them to do or that the Home Office might ask them to do would put them in a position where they would be at risk.

Earl of Onslow: Do you get the right backup from the police and all the other people who are supposed to give you backup? You do not receive any complaints about this, do you?

Chairman: I do not think you ought to answer that question. Perhaps we could turn to a crucial question.

Earl of Onslow: Actually, my Lord Chairman, I think it is very, very important. If we ask public servants to do something, they have to be able to do it, and I hope that they are. If they are not, I suggest that we should be entitled to say, "Why, oh Home Secretary, or Home Chief Inspector, or Superintendent of the Metropolitan Police, are you not giving these guys the proper backup which they deserve?"

Chairman: With respect, Lord Onslow, I do not necessarily disagree with what you are saying, but I thought that Dr Richmond had more or less answered your question previously.

Earl of Onslow: Fair enough.

Chairman

143. Turning to the next question, this is a crucial question about the cost/benefit assessment in practice. What factors are taken into account and how are they balanced? Could you give us one or two examples, please, Dr Richmond?

(*Dr Richmond*) The inspector conducts more than a simple cost/benefit assessment. We are not simply establishing that the potential benefit exceeds the potential welfare cost; we are also ensuring that the legislative requirements are met which in part do not reflect a strict cost/benefit assessment. We are ensuring that various administrative requirements are implemented and we are ensuring that even though the potential benefit seems to exceed the welfare cost, there is no strategy to reduce the likely welfare costs in cases where animals are to be used. In terms of the potential benefits, the first thing we consider is, is this programme of work likely to succeed, that is, is the programme of work as outlined likely to realise the specific objectives declared on the application? In terms of potential benefit, we consider the use that will be made of the knowledge or product that will result from the use of the animals. We consider that to be the potential benefit, not strictly speaking the importance of the field of work in which the application is operating, and in terms of potential cost we regard the animal welfare costs as something calculated by weighing things such as the species being used, the numbers of animals being used, the stage of development of the animals being used, the interventions being performed, the endpoints being applied. We have published details of this. The best reference material for you to refer to would be my report of 1997 which is published as part of the APC Annual Report for that year.

Lord Taverne

144. I am afraid I have not read the report of 1997, but when you say that you look at the use that has been made of the animal experiments, is this not something which is rather difficult to judge when you are dealing not with applied experiments or anything which is happening in industry, but with academic curiosity, when you are dealing with pure research? So much research is done which can be extremely interesting and may turn out to be enormously important, but that at the time nobody knows how it is going to be applied. How do you judge academic curiosity? In this line, what about the cases where the benefit is corporate profit? How do you balance corporate profit against animals suffering?

(*Dr Richmond*) My Lord Chairman, taking the second point first, we do not regard corporate benefit as a reasonable benefit for the cost/benefit assessment under the Act, and again there is a part of the review which we published explaining what we do. In the distinction you were drawing between applied and fundamental research, in fact the opposite is probably true. When we focus on the use that will be made of the information from an individual study, the gap between applied and fundamental research shrinks dramatically, because even with new healthcare technologies the role of any single experiment or any single programme of work in getting new technology into the healthcare is simply another step along the way, rather than all that is required to produce the benefit. We regard academic curiosity and intellectual curiosity as not necessarily a bad thing, providing the intention is actually to generate new knowledge and to share it with others.

145. If I may take a typical example, research into malaria may be extremely remote from actually producing a vaccine, it may simply be research into the effect, the structure, of particular mosquitoes. All right, that probably is not going to lead to animals suffering, because we are not so much worried about insects, but how far can you actually say that there is a benefit just because one is looking at something which is where the benefit can be extremely remote?

(*Dr Richmond*) We would be prepared to consider anything which increased knowledge of the biological sciences for which other people might be able to find an application as a particular benefit.

Lord Brennan

146. Are these criteria publicly available?

(*Dr Richmond*) My Lord Chairman, the most recent contemporary summary is the 1997 APC Annual Report which does contain a detailed paper on how the cost/benefit assessment not only is done at present but has evolved since the Act was introduced.

Chairman: I think that I should, on behalf of the insects, say that Lord Taverne has not pre-empted our Inquiry by his statement.

Lord Lucas

147. What is the fundamental ethical foundation on which you lay that comparison? To take the example of mouse papers, which I have used before, where people lay down these sticky traps to trap mice in restaurants, and mice will injure themselves, tear legs free and die from starvation over hours in great pain, in order to stop people getting a bit of mouse excrement in their cornflakes, which is something people have lived with for generations, you are presumably faced with similar sorts of balancing acts. What system of ethics underlies this? How do you weigh human benefit against animal suffering?

(*Dr Richmond*) We apply a consequentialist, utilitarian cost/benefit assessment, which means that we cannot measure it in strictly mathematical terms, but we try to quantify and categorise the potential benefit and the potential animal suffering. We have a database of policy and precedent which we find very helpful. Applications tend to fall into three general categories: those where the potential benefit clearly outweighs the potential cost—and again those are fairly straightforward; those where the potential cost quite clearly seems to exceed the potential benefit—and again the course of action is quite clear in this case; and the more difficult ones where things are more finely balanced, and that is where we rely on the professional judgement of the inspectors to come to a decision about what the true welfare costs are, what the true scientific merits are and how those things fit in with what we have previously considered to meet the required cost/benefit assessment.

Earl of Onslow

148. So what you are saying is that the life of a rat in a research laboratory is much happier than the life of a rat in my stables where I can chuck strychnine at it, a cat, a dog, a shovel or a broomhead to make sure that it exits from this world as quickly and rapidly as possible. The rat in your laboratory is going to have a much easier and a much happier life, is that reasonable to say?

(*Dr Richmond*) There are some people, my Lord Chairman, who have argued exactly that.

Chairman

149. Perhaps we could move on to a related question on the cost/benefit point. Is the principle of the cost/benefit assessment compatible with the rule that no animal may undergo general anaesthesia more than once? Is this rule appropriate for large animals (such as horses) as well as for small animals?

(*Dr Richmond*) My Lord Chairman, this revolves around section 14 of the Act, which allows under specific circumstances the Secretary of State to allow animals to be reused. That section of the Act overrides what would otherwise be a blanket prohibition on the reuse of animals. The control is not exactly as stated in your question. Animals may have more than one, more than two, more than three anaesthetics. Section 14 actually says that when the first use of an animal is finished—that is, when the experiment is completed—if, during the course of the experiment, the animal had an anaesthetic, unless the anaesthetic was simply to allow a surgical preparation, or simply to restrain the animal while something non-painful was done, they only then may be reused under general anaesthesia and without recovery. However, if you have a procedure or an experiment that requires that an animal has several anaesthetics in order that that procedure can be

Chairman *contd.*]

completed, then section 14 does not apply and animals may be subjected to more than one general anaesthetic.

150. I was wondering later should inspectors be trained to deal with licence applications relating to only one type of animal? How would this improve the standardisation of inspections across the country?

(*Dr Richmond*) My Lord Chairman, I would say that we have considered a number of structures and strategies in the past: by animal type, we have not considered; by the class of application we have. However, we find that one of the things which is invaluable in dealing with applications is a local knowledge of the place, the people, the research group and its track record, so we prefer applications to be considered in the first instance by an inspector who knows the establishment, who can then refer it internally to our internal expert for further advice.

Lord Taverne

151. I believe from the figures that only about one-third of animal procedures are conducted under anaesthetic, is that correct?

(*Dr Richmond*) That is approximately correct, yes.

152. Why is that figure so low, may I ask? How do you decide whether anaesthesia or painkillers are required in an experiment?

(*Dr Richmond*) The legislation requires that anaesthesia and analgesia be used unless they would produce a greater insult than the procedure that is actually being performed, or unless they would frustrate the scientific objective of the study. The vast majority of the two-thirds of procedures which are conducted without anaesthesia are fairly simple and straightforward minor interventions—dosing animals with test materials, taking blood samples, dietary studies, things where the intervention is less traumatic than the giving of an anaesthetic.

153. You say that that is required unless it frustrates the purpose of an experiment. Does that mean there are cases where severe suffering would be caused, but the use of anaesthesia would frustrate the purpose of the experiment, and you might say, "Look, the suffering is too great. However beneficial this experiment may be, we're not going to allow it"?

(*Dr Richmond*) Yes, the legislation will not permit anything happening which would cause severe pain and distress which cannot be relieved. We would never, under any circumstances, consider recommending that the Secretary of State authorise surgical procedures without the appropriate anaesthesia.

154. Taking a particular example, I remember that somebody studying blindness did some experiments on kittens—not necessarily taking out the eyes of the kittens, but blinding the kittens and obviously causing them severe distress. Obviously the experiments were allowed. On what basis would you judge a case like that?

(*Dr Richmond*) I think we would have to be satisfied that no unnecessary distress was being caused, and that the potential scientific benefit was sufficient to offset any suffering which was caused.

Lord Lucas

155. I wondered if you could—not now—let us have sight of some cost/benefit analyses, particularly ones near the margin like that, where there is considerable cost, so that we can understand how the judgement is taken in practice and get a feeling for the sort of database, as you expressed it, of past experience?

(*Dr Richmond*) Do you want to take that, Mr Cobley?

(*Mr Cobley*) No, I think it is yours.

(*Dr Richmond*) I am not trying to duck the question of responsibility, but advice to Ministers is generally regarded as something which is not disclosed, and that is part of the assessment.

Earl of Onslow: Surely, with the greatest of respect, that is such a cop-out; it is the sort of excuse I would give if I was trying to get out of it.

Chairman: You should take that as a compliment.

Earl of Onslow

156. Surely you could go to your Minister and say that there is this array of very serious, grown-up humanoids asking you questions, "and they want to help you, oh Minister. Please can we give them, without the names of the people, take out anything confidential, an example of how we can do it?" Of course you can do that.

(*Dr Richmond*) However, my Lord Chairman, we have prepared other material for teaching and other purposes, which has been suitably anonymised, and you might find that useful.

Chairman: We will. Thank you very much indeed.

Baroness Eccles of Moulton: There is one thing I might have misheard when you were answering one of the questions on severe pain and cost/benefit. Did you say that in an extreme case the severe pain that could be caused to the animal would outweigh a very, very strong benefit to medicine, or did I mishear that?

Earl of Onslow

157. I hope that is the case.

(*Dr Richmond*) These things are looked at case by case, and it would depend on the specific welfare cost and the specific potential benefit which would be likely to arise.

Baroness Eccles of Moulton

158. So the balance could tilt on the side of benefit to medicine—human medicine—that would outweigh extreme suffering to an animal?

(*Dr Richmond*) But not to the extent of allowing an animal to experience severe pain or distress which could not be alleviated.

159. Which could not be alleviated. That is the bit I find difficulty with. You can alleviate extreme pain and suffering by simply putting it out of its misery, having done the experiment, can you not?

(*Dr Richmond*) You can do that, but there are some experiments which you can envision which can only be achieved by causing severe pain and distress that could not be alleviated, and the legislation as it

Baroness Eccles of Moulton *contd.*]

stands would not permit those experiments to be conducted?

160. So are we talking about over a period of time?

(*Dr Richmond*) The legislation is not specific.

Baroness Eccles of Moulton: No. Thank you. I am still not entirely comfortable with the possible way that the balance could be tilted against progress in medicine for the benefit of humans, but obviously you have given me all the answer you can, thank you.

Lord Soulsby of Swaffham Prior

161. It is true, is it not, that where there is the necessity for an anaesthetic for the purposes of avoiding severe pain, the animal is not allowed to recover, as a general principle, and it is only under very rare circumstances that you would allow recovery and an assessment of whatever the procedure would be, like on the basis that once an animal has suffered an experiment of whatever it is, with an anaesthetic or not, it has served its time, as it were, and you do not put it through another set of experiments at all?

(*Dr Richmond*) As a general rule, that is true, but section 14 of the Act does allow reuse under specific circumstances. We tend to take the view, in advising the Minister on section 14, that any animal which has experienced any significant suffering as part of the first use should not be reused.

Earl of Onslow

162. Am I not right—and I am only going, I think, on hearsay—that before the Falklands the army doctors, perfectly reasonably, wanted to practise on wounds, so they shot up a lot of pigs under general anaesthetic, they sewed them all up and they did all their stuff to practise on putting them together, but they did not allow those pigs to recover from the anaesthetic? Would it be possible, in your view, to say, going back to the point, I think, that Lady Eccles was making, that actually it is arguable that, even though those pigs did not suffer very considerable discomfort—I mean, being shot at with a rifle does you no good at all—their recovery from the wound after the sewing up or the repair thereof might be a very great scientific benefit? I accept I am asking a question about which I do not know the details, I am dragging it out from the bottom of my mind, from something I know, but it does seem to me that it goes, I think, to the point that Lady Eccles was making.

(*Dr Richmond*) My Lord Chairman, the Act describes certain permissible purposes for which animals may be used, and education and training is one of those purposes. To date the Home Office has separated education and training, believing that education is teaching people principles, giving them the knowledge, helping them develop the required skills to formulate and evaluate hypotheses, and that training is the teaching of manual skills. The only training licences which have been issued are to train clinical surgeons in microvascular surgery techniques. That was an assurance given to the House of Commons when the legislation was debated.

163. The legislation is post-Falklands anyway, is it not?

(*Dr Richmond*) That is right. The work you are talking about was not done in this country, and I believe it was done with the pigs under anaesthesia from beginning to end.

Earl of Onslow: That is what I thought too.

Chairman

164. We now come to the last three questions which refer to both the ABCU and to the Animals Inspectorate. What changes, if any, would you like to see made in the Act or its implementation?

(*Mr Cobley*) As I think we indicated in our memorandum, my Lord Chairman, we do not at the moment envisage any changes in the Act. I mentioned the review of section 24. Obviously if that gave rise to some agreement to amend that section, then we would do that, which we can do by using order-making powers under the Freedom of Information Act. There is also a likely review of the European Directive to which Dr Richmond referred earlier on. Again, if that threw up some need to amend our legislation, then clearly we would need to do it. However, we do regard the Act as a flexible instrument. We can make changes, for example, to the schedules—Schedule 1, methods of humane killing—by order-making powers. In fact, we have recently asked the Animal Procedures Committee to review Schedule 1, and obviously if they come up with some changes which Ministers agree to, then we can do that by secondary legislation.

Baroness Nicol

165. I think Mr Cobley has just qualified what he said at the beginning. I was very alarmed to hear that we had the perfect Act here—

(*Mr Cobley*) I am not saying that

166. —and that there is no change that can be made either by addition or deletion that can please you. Is that what you are saying really?

(*Mr Cobley*) No, I am saying that the Act is flexible and can be adapted in terms of the primary purposes. Obviously in terms of implementation, which I think was the other point in your question, we keep that under continual review, and we described today some of the ways in which we are changing the way we implement it.

Lord Taverne

167. Is there any major pressure to change the Act, either from the scientific community or from the animal rights lobbies, as it were?

(*Mr Cobley*) I am sure the anti-vivisectionists, were they before you, would be wanting to make a fundamental change.

168. No, but the non anti-vivisection animal welfare pressure groups seem to be quite satisfied with the Act?

(*Mr Cobley*) I am not aware of any other pressure to amend the Act.

Lord Taverne *contd.*]

(*Dr Richmond*) I think there is greater interest in the community we are regulating and how it operates, rather than the Act itself. I think there is general agreement that the general principles which underpin the Act—which are that the work must be justified, that it cannot be refined—are things that the scientific community also share and things they think are reasonable and that the public think are reasonable ways of controlling animals in science.

Earl of Onslow

169. You see no benefit in my suggestion that it is institutions which should be licensed and given a very broadbrush approach to what they do, in section guidelines, rather than you at the Home Office regulating exactly which experiments should be done? I must admit, I think that my view is probably a minority one, but I think it is still the best one.

(*Mr Cobley*) I do not think I want to go any further than I have done, my Lord Chairman.

Chairman: I think it is an attempt to bushwhack you a second time.

Lord Brennan

170. I would like to provoke some enthusiasm for reforming it. The question invites consideration of whether there should be a change to the Act or to its implementation. I am going to invite you to consider one change and some general reform of implementation. Analysing what you have been telling us this afternoon, the function of your Inspectorate and Civil Service bodies is threefold, it seems to me: one is efficiency and competence; two is bureaucracy and cost; three is information and confidentiality. I am greatly reassured by what you have told us about the first two, but I am extremely concerned about the third, because it is the bridge to the consequences of your operations, and the consequences are threefold: one, public perception; two, the protection of academic and business research to the benefit of medicine and the public; three, deterring animal rights movements such as we are now suffering from. With that analysis in mind, if we are to avoid a bunker mentality where the Act is kept the way it is, secrecy prevails, confidentiality is the way to avoid trouble from animal rights people, surely things are only going to get worse? The way better to inform the public, better to protect business and academia, to deter animal rights people, is to change section 24 in a way in which the onus favours publication of material unless there is some good reason why not, and then in the implementation of the Act to give the maximum of information in the most public way possible—web sites, meetings with the Royal Society for the Prevention of Cruelty to Animals, television programmes, everything you can think of. That involves consideration of section 24 and it involves your unit principally, it seems to me, in adopting a new ethos of telling people what is going on. Do you agree?

(*Mr Cobley*) I think I have already said that Ministers are reviewing section 24. They will be attempting to maintain this balance between greater openness and confidentiality and personal security which they obviously attach extreme importance to as well. I have mentioned the possibility of publishing lay summaries of the project licence applications as an example of how we might be able to find a way through this, because I accept what you say that over-confidentiality does no one any good at all.

171. Can I reassure you and the Minister that the thing that comes into mind is that the establishment which is your equivalent in the United States has both its inspection reports and research applications available under the Freedom of Information Act, and in that country there is 70 per cent acceptance of the use of animals for medical research.

(*Mr Cobley*) Yes.

(*Dr Richmond*) To qualify what has just been said, it is true indeed that the USDA's reports are publicly available, but the Animal Welfare Act, which is the relevant US regulation, does not regulate the use, care and accommodation of rodents and birds, and the federal agency has no knowledge of the science that is being done and is therefore not in a position to disclose what is actually being done in laboratories, whereas in this country we know in great detail what research groups and industry are planning for the next five years, and that is what concerns users in this country.

Lord Brennan: Which should help to improve the figure here beyond 70 per cent.

Chairman

172. Mr Cobley, if we were to invite you back again, towards the end of our deliberations, you would be able to tell us how much ministerial opinion has progressed in this regard?

(*Mr Cobley*) Yes indeed, my Lord Chairman.

173. Finally—our last question, I think, which is about costs in a financial sense rather than other costs—how are the fees charged to research establishments calculated; and how are these monies divided between the Animals Inspectorate, the Animal Procedures Committee, the ABCU and the funding of research into alternatives to animal procedures?

(*Mr Cobley*) Mr Walsh is going to respond to that.

(*Mr Walsh*) My Lord Chairman, the Treasury rules require that we recover the full costs of running the inspection and licensing system, also the full costs of the Animal Procedures Committee and its research expenditure. In the current year they have a budget of £280,000 for research into alternative use. There are three separate fees charged. Fees are charged for personal licences, user establishments pay for their certificate of designation, and breeding establishments pay a similar charge for their status. The bulk of the income derived from fees actually comes from personal licences of which there are something like 13,000. There is no hypothecation of the fee income—60 per cent goes to the Consolidated Fund and 40 per cent goes into Home Office receipts—so it is more a cost recovery exercise rather than getting income in in order to pay for current activities.

Chairman *contd.*]

Earl of Onslow: So it is a tax? If it goes into the central Treasury, it is a tax, and "no hypothecation" means it is a tax; it is ship money, it is circa 1641.

Chairman: That is for the record, for the erudition of us and to establish Lord Onslow's credentials as a financial historian.

Lord Taverne

174. About the £280,000 spent on alternatives to animal procedures, is there any point in spending that money? First of all, it seems so little that it cannot have much effect. Secondly, is not the main incentive anyway that nearly every scientist would find it much easier, much more convenient, not to use animals at all, so there is always a constant incentive to try to find alternatives to animal procedures, is there not?

(*Mr Walsh*) The Chief Inspector will probably comment on the latter point. This is not the only amount of money that is spent on alternative research in Government as a whole. Other departments—who presumably will at some point, my Lord Chairman, appear or be invited perhaps before you—can perhaps explain the level of expenditure they input into alternatives, but some estimates that we obtained, I think, about two years ago indicate that somewhere in the region of perhaps £2 million across Government was spent on alternative research, which is obviously more significant than £280,000. I think the Chief Inspector will probably confirm that a great deal of effort goes in, in the scientific community, to find alternatives.

(*Dr Richmond*) My Lord Chairman, the bulk of work which is done on alternative methods is actually done by science and industry, not by those who campaign against the use of animals in experiments. The methods we talk about as alternatives are generally the more advanced methods; not only do they provide better science, usually at lower cost, but usually quicker and easier science as well. The scientific community works hard to find alternatives and embrace them as advancements rather than alternatives. Within the last week I have been speaking to the Directors of the European Centre for the Validation of Alternative Methods, and to the American equivalent at ICCVAM which is the US validation service, who were lamenting that one of their concerns at the moment is the paucity of good ideas coming forward for development and validation as alternative methods.

Lord Lucas

175. None the less, we have no professorships in alternatives, we have no status given to people who do research into that. Indeed, what we are running into with Europe is a whole collection of new animal experiments to validate old chemicals. Do we have no list of procedures which we can determine to find alternatives for within Government?

(*Dr Richmond*) My Lord Chairman, we look critically at the annual statistics every year, trying to identify the priorities. I think the priorities should be the larger numbers, the higher species and the greater suffering. We do try, through the Home Office funding of research, to make sure that money is actually targeted with those priorities in mind.

Lord Soulsby of Swaffham Prior

176. I think every biological scientist is always looking for better and alternate ways of doing something, which give a better result to what he wants to do and makes life cheaper too, because scientific research is quite expensive and animals are a major portion of that cost. Nevertheless, the figure of £280,000 is designated as research on animal alternatives, and to my mind it gives an impression that we are not too concerned about looking for alternatives. If there is £2 million spent, I would like to know how that is calculated, because that is a new figure to me, that £2 million is spent on looking for alternatives. It may well be within the scientific biological community that that amount is spent, but we have a figure of £280,000 here, and it seems a paltry amount. That is about four or five grants looking for alternatives. We have always felt that that figure should be very much higher if one really does believe that there are alternatives to animal research, and that that figure should go up very, very substantially to help not only us but ECVAM too—I know they are short of money as well—but it is designated as such and it creates a poor impression, quite frankly.

(*Dr Richmond*) My Lord Chairman, I think that when you take evidence from industry and academia you will find that they are investing substantial sums in alternative technologies, and you may want to bear that investment in mind when you compare it with the Home Office investment.

Lord Soulsby of Swaffham Prior: Thank you. If it is a figure of £2 million, I would say "Hallelujah." That is good news, but £280,000 is not good news.

Chairman

177. Thank you all very much. Are there any points you would like to make, gentlemen, which we have not raised and which you would have liked to have raised?

(*Mr Cobley*) No, I think we have covered the ground very adequately, my Lord Chairman.

Chairman: Thank you all very much for coming.

Supplementary Memorandum by the Chief Inspector, ASPI

As requested, I write to confirm the changing use of Inspectorate resources (see Q. 130).

Prior to the 1986 Act animal research was regulated by the Cruelty to Animals Act 1876. Licences and certificates issued under the act provided comprehensive technical authorities. There was no equivalent of the current project licence: in fact the regulatory system and the regulatory decisions were taken more with respect to the applicant than the programme of work. The Inspectorate was smaller than it is now (17 professional staff): all were medical or veterinary graduates, but a strong background in biomedical research was not a requirement. Typically an inspector would spend two days a week on licensing and administration, and three days a week on inspection related activities.

The 1986 Act introduced the project licence and places an obligation on the Secretary of State to ensure (amongst other things) the animal work is only licenced, if it passes a cost/benefit assessment, if not replacement alternatives exist, and if all appropriate strategies to minimise the number of animals used and to refine to the procedures to be applied are invoked. The Secretary of State generally exercises his judgement on these matters on advice from the inspectorate.

With the introduction of the 1986 Act the Inspectorate was expanded (first to 19 then to 21) with the emphasis being upon recruiting medical and veterinary graduates with first hand experience of quality biomedical research. Over the years the level of inspectorate manpower fluctuated in line with changes in financial provision. When I was appointed Chief Inspector we had 14 professional staff: that was increased to 17, then to 21. Ministers recently announced (as detailed elsewhere in the Home Office evidence) the appointment of an additional 12 staff over the next three years.

Casework is demand led, with approximately 600 project licence applications being considered each year. As the biological sciences become increasingly complex, the time and effort required to assess applications has also increased. In order to maintain defensible processing times, time is varied between assessment of applications and the inspection programme. At present, typically, inspectors spend 45 per cent of their time on assessment activities (which can include site visits to discuss proposals): the bulk of this resource is in practice deployed to identify and negotiate improvements both to the science and the animal welfare costs of the proposals (a supplement to the Home Office annual statistics for 1998 provided 10 detailed examples). 40 per cent of their time in inspection related activities. (The remaining 15 per cent is spent on continued professional development and general administration.) Management information reveals this has been the pattern for the past three years.

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